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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/679,520 | 10/06/2003 | Sheena May Loosmore | 454313-3161.4 | 7647 |

20999 7590 04/15/2009
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| EXAMINER | |
|---|---|
| POPA, ILEANA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1633 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 04/15/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| | | |
|---|---|---|
| ***Office Action Summary*** | **Application No.**<br>10/679,520 | **Applicant(s)**<br>LOOSMORE ET AL. |
| | **Examiner**<br>ILEANA POPA | **Art Unit**<br>1633 |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *23-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22, 29, and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 23-28 have been withdrawn. Claims 1, 5, 10, 29, and 30 have been amended.

Claims 1-22, 29, and 30 are under examination.

2. The provisional rejection of claims 1-22, 29, and 30 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-22, 29, and 30 of copending Application No. 10/714,781 in view of amendments to claim 1 in the '781 application, which amendments were filed on 11/06/2008, i.e., after the mailing date of the non-final rejection in the instant application which is 08/01/2008. In view of these new amendments in Application No. 10/714,781, a new obviousness-type double patenting rejection is made below.

The following rejections are withdrawn in response to Applicant’s amendments to the claim filed on 02/02/2009 to delete the recitation of "plasmid" from the claims:

The rejection of claims 1, 7, 13, 15-18, 22, 29, and 30 under 35 U.S.C. 102(e) as being anticipated by Chang (U.S. Patent No. 7,227,011), as evidenced by Chang et al. (J Virol, 2000, 74: 4244-4252);

The rejection of claims 1, 7, 10, 11-14, 15-20, 22, 29, and 30 under 35 U.S.C. 103(a) as being unpatentable over Chang taken with Chang et al., in view of Mumford et al.;

The rejection of claims 1, 7, 10-13, 15-18, 21, 22, 29, and 30 under 35 U.S.C. 103(a) as being unpatentable over Chang taken with Chung et al., in view of Ruitengerg et al.;

The rejection of claims 1-13, 15-18, 22, 29, and 30 under 35 U.S.C. 103(a) as being unpatentable over Chang taken with Chung et al., in view of both Paoletti and Paoletti et al.

## *Response to Arguments*

### *Claim Rejections - 35 USC § 112, 1st paragraph – written description*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1"Written Description Requirement" makes it clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosures of relevant, identifying

characteristics, i.e., structure or other physical and or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that the Artisan can reasonably conclude the inventors had possession of the claimed invention. Such possession may be demonstrated by describing the claimed invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and/or formulae that fully set forth the claimed invention. Possession may be shown by an actual reduction to practice, showing that the invention was “ready for patenting”, or by describing distinguishing identifying characteristics sufficient to show that the Applicants were in possession of the claimed invention (January 5, 2001, Fed. Reg., Vol. 66, No. 4, pp.1099-11).

Claims 10-12 are drawn to nucleic acids as defined in GenBank accession no. AF196835. It is noted that GenBank accession numbers are constantly updated or taken out, and therefore, one of skill in the art would not recognize that a reference to a GenBank accession number satisfies the written description requirement. The genus of sequences identified by GenBank accession no. AF196835 is constantly changing; the genus encompasses future sequence versions identifiable by the same GenBank accession number, wherein the new versions could comprise variants of the sequence recited in the claims. For these reasons, one of skill in the art would not recognize that Applicant was in possession of the entire genus of nucleic acids as defined by GenBank accession no. AF19683. Version AF19683 recited in the claims represents only a specific embodiment of the genus of nucleic acids identified by GenBank accession no. AF19683 and there is no guarantee that this version is not going to be replaced by updated sequences. For these reasons, one of skill in the art would not recognize that Applicant was in possession of what is claimed.

Claim 1 has been included in the instant rejection because claims 10-12 depend from it; therefore, claim 1 encompasses the embodiment under rejection.

If Applicant considers such a reference sequence essential, reference to the appropriate SEQ ID NO: may be made.

Applicant submits that claim 10 has been amended to include the appropriate SEQ ID NO., as suggested by the Examiner. This amendment is acknowledged, however, the rejection is maintained because the reference to the GenBank accession no. AF19683 has not been deleted and therefore, the claims encompass the embodiment under rejection. To obviate the instant rejection, Applicant must delete the reference to the GenBank accession no. AF19683 from claim 10.

## ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-11, 16-18 and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti (Proc Natl Acad Sci USA, 1996, 93: 11349-11353), in view of each Goverdhan et al. (Acta Virol, 1992, 36: 277-283), Ostlund et al. (Vet Clin North Am Equine Pract, 2000, 16: 427-44, Abstract), and Paoletti et al. (US Patent No. 5,756,103).

Paoletti teaches a method of inducing an immunological response against Japanese encephalitis virus (JEV) by administering to a subject an immunogenic composition comprising NYVAC and recombinant canarypox (i.e., ALVAC, see also Paoletti et al., US Patent No. 5,756,103, Fig 17, Fig. 31, and Example 15) encoding the polyprotein prM/M, E of JEV (p. 11351, column 2 bridging p. 11352, column 1) (claims 1-9, 17, and 18). Paoletti et al. do not teach West Nile virus (claims 1-9, 17, and 18). However, Goverdhan et al. teach that JEV and West Nile virus are antigenically-related and are capable of eliciting cross-immune responses; they also teach that immunization with JEV protects animals against West Nile virus infection (Abstract, p. 278, first paragraph, p. 281, second full paragraph). Based on these teachings, one of skill in the art would have known that the JEV and West Nile virus prM/M, E polyprotein, similar to the JEV prM/M, E polyprotein, could be used in the vaccine of Paoletti. It would have been obvious to one of skill in the art, at the time the invention was made, to modify the vaccine of Paoletti by substituting their JEV prM/M, E with the West Nile virus prM/M, E, to achieve the predictable result of obtaining a vaccine against West Nile virus. It is noted that such an anti-WNV vaccine would necessarily comprise the nucleotide sequences recited in claims 10 and 11, since, at the time the invention was made those sequences were already deposited as GenBank AF 196835. Paoletti and Goverdhan et al. do not teach immunizing a horse (claims 16 and 22). However, at the time the invention was made, the prior art taught the necessity of vaccinating horses against West Nile virus (see Ostlund et al., Abstract). Therefore, it would have been obvious to one of skill in the art, at the time the invention was made, to use the vaccine of Paoletti and Goverdhan et al. to immunize horses, with a reasonable expectation of success. One of skill in the art would have been motivated to do so because Ostlund et al. teach that West Nile virus poses a threat for disease occurrence in horses (see Abstract). One of skill in the art would have been expected to have a reasonable expectation of success in making and using such a composition because the art teaches that such composition can be successfully obtained and used to elicit immune responses in animals. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

7. Claims 1-12, 16-18, 22, 29, and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with each Goverdhan et al. Ostlund et al., and Paoletti et al., in further view of both Stocks et al. (J Virol, 1998, 72: 2141-2149, of record) and Chang et al. (J Virol, 2000, 74: 4244-4252, of record).

The teachings of Paoletti, Goverdhan et al., Ostlund et al., and Paoletti et al. are applied as above for claims 1-11, 16-18, and 22. Paoletti, Goverdhan et al., Ostlund et al., and Paoletti et al. do not teach a signal peptide (claim 12). Stocks et al. teach the importance of adequate posttranslational processing of prM for the immunogenicity of the vaccine (p. 2141, column 2, first paragraph). Chang et al. teach the inclusion of the signal peptide of prM in their anti-JEV vaccine for proper processing of prM (p. 4245, column 1, first paragraph, p. 4249, column 2, first and second paragraphs, and p. 4249, column 2 bridging p. 4250). It would have been obvious to one of skill in the art, at the time the invention was made, to include the prM signal peptide in the recombinant vaccine, with a reasonable expectation of success. The motivation to do so is provided by both Stocks et al. and Chang et al., who teach the lack of immunogenicity for constructs not optimized for proper processing of prM. One of skill in the art would have been expected to have a reasonable expectation of success in making and using such a vaccine because the art teaches the successful use of signal peptides in vaccines directed against flaviviruses. It is noted that such an anti-WNV vaccine would necessarily comprise the nucleotide sequences recited in claim 13, since, at the time the invention was made those sequences were already deposited as GenBank AF 196835. With respect to the limitation of plasmid (29 and 30), Paoletti taken Goverdhan et al. and Ostlund et al. do not teach it. Chang et al. teach plasmid-based anti-JEV vaccines (Abstract, p. 4244, column 2). It would have been obvious to one of skill in the art, at the time the invention was made, to use a plasmid DNA vaccine as taught by Chang et al., with a reasonable expectation of success. The motivation to do so is provided by Chang et al. who teach that a single injection with plasmid DNA vaccine induced a virus-specific antibody response, as compared to vaccination using a virus that require multiple immunizations (p. 4244, column 2). One of skill in the art would have been expected to have a reasonable expectation of success in making and using such a vaccine because Chang et al. teach the efficiency of plasmid-based vaccines to induce a robust antibody response. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

8. Claims 1-11, 13, 14, 16-20, and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with each Goverdhan et al., Ostlund et al., and Paoletti et al., in further view of Mumford et al. (Epidemiol Infect, 1994, 112: 421-437, Abstract, of record).

The teachings of Paoletti, Goverdhan et al., Ostlund et al., and Paoletti et al. are applied as above for claims 1-11, 16-18, and 22. Paoletti, Goverdhan et al., Ostlund et al., and Paoletti et al. do not teach a carbomer as an adjuvant (claims, 13, 14, 19, and 20). Mumford et al. teach carbomer. It would have been obvious to one of skill in the art, at the time the invention was made, to use carbomer as an adjuvant, with a reasonable expectation of success. The motivation to do so is provided by Mumford et al. who teach that horses were protected against equine influenza when vaccinated in the presence of carbomer, as compared with other adjuvants. One of skill in the art would have been expected to have a reasonable expectation of success because Mumford et al. teach the efficiency of such an adjuvant. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

9. Claims 1-11, 15-18, and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al., Ostlund et al., and Paoletti et al., in further view of Varga et al. (Veterinary Microbiol, 1997, 56: 205-212, of record).

The teachings of Paoletti, Goverdhan et al., Ostlund et al., and Paoletti et al. are applied as above for claims 1-11, 16-18, and 22. Paoletti, Goverdhan et al., Ostlund et al., and Paoletti et al. do not teach a bivalent vaccine (claim 15). Varga et al. teach a bivalent vaccine comprising EHV-2 and *R. equi* serotype 1 strain to protect horses from infection by both viruses (Abstract, p. 20, p. 210, Discussion). It would have been obvious to one of skill in the art, at the time the invention was made, to use bivalent vaccine, with a reasonable expectation of success. The motivation to do so is provided by Varga et al. who teach that protection against two different viruses can be achieved by using a bivalent vaccine. One of skill in the art would have been expected to have a reasonable expectation of success because the art teaches the successful use of multivalent vaccines to achieve protection against different pathogens. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

10. Claims 1-11, 16-18, 21, and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken Goverdhan et al., Ostlund et al., and Paoletti et al., in further view of Ruitengerg et al. (Vaccine, 2000, 18: 1367-1373, of record).

The teachings of Paoletti, Goverdhan et al., Ostlund et al., and Paoletti et al. are applied as above for claims 1-11, 16-18, and 22. Paoletti, Goverdhan et al., Ostlund et al., and Paoletti et al. do not teach prior administration of a WNV isolated antigen (claim 21). Ruitengerg et al. teach a better protection by administering to the subject a plasmid encoding EHV-1 glycoprotein D, followed by a recombinant virus expressing the glycoprotein D (Abstract, p. 1367 bridging p. 1368). It would have been obvious to one of skill in the art, at the time the invention was made, to use such an immunization scheme, i.e., to obtain protection against WNV by administering to the animal a plasmid encoding for a WNV antigen or an isolated WNV antigen followed by a recombinant anti-WNV vaccine, with a reasonable expectation of success. The motivation to do so is provided by Ruitengerg et al. who teach that a better protection against can be achieved in this way. One of skill in the art would have been expected to have a reasonable expectation of proper protection against pathogens. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Applicant traversed all rejections above on the grounds that one of ordinary skill in the art would not combine Goverdhan et al. with Paoletti. Applicant argues that Goverdhan et al. relate to WNV vaccines comprising formalin-killed WNV, and do not teach or suggest any WNV antigen or epitope that plays a role in an immunogenic response. A killed virus vaccine is significantly different from a recombinant virus, as recited in the instant claims and in Paoletti. To emphasize this point, Applicants invite the Examiner to refer to the enclosed article by Schultz et al. (Intervirology 2000, 43:197-217) which addresses some of the unique considerations that must be observed when using DNA vaccines, as opposed to killed virus vaccines. This document demonstrates that DNA vaccines and killed virus vaccines could not be considered equivalent at the time of the invention. Moreover, Schultz et al. discusses the unpredictability of and difficulties associated with DNA vaccines. Therefore, Applicant argues, the skilled artisan could not apply teachings based on killed virus vaccines to recombinant virus vaccines. Applicant reiterates that there is no teaching or suggestion as to whether there are any particular antigens or epitopes of the killed virus that can be applied to the recombinant vector vaccines. Applicant asserts that transposing results between JEV and West Nile virus is, at best, unpredictable. In Goverdhan et al., the JEV vaccine resulted in a protective immune response against challenge with WNV. In contrast, the WNV vaccine resulted only in a reduction of the severity of the disease following challenge with JEV (see abstract). Given these results, the skilled artisan could not predict the response in combining Paoletti and Goverdhan et al. and substituting JEV polyproteins for WNV polyproteins.

Applicant also argues that the unexpected results associated with the claimed invention have not been fully considered. Applicant reiterates that the present invention provides surprising and unexpected results that enjoy real world success. Applicant brings attention particularly to Example 32 of child application Serial No. 10/714,781 (a continuation-in-part of the present application) wherein one dose efficacy of a canarypox vectored West Nile Virus vaccine (vCP2017) against a WNV-infected mosquito challenge in horses was described, wherein 1/9 vaccinated horses developed detectable West Nile virus viremia (11.1%), whereas 8/10 control horses (unvaccinated) developed detectable viremia (80%) post challenge. For at least the reasons presented above, the claimed invention is not obvious over the cited references.

Applicant's arguments are acknowledged, however, the rejection is maintained for the following reasons:

It is noted that most of the Applicant's arguments are not new (specifically that Goverdhan et al. teach formalin-killed WNV, that the WNV vaccine utilized in Goverdhan was significantly less protective than was the JEV vaccine, and unexpected results) and were previously addressed. With respect to the argument of unexpected results, Applicant argues that the Examiner did not consider them. This is incorrect. As noted above, and as Applicant admits by reiterating them, these arguments were previously presented and completely answered in the non-final Office action of 02/12/2007.

With respect to Schultz et al., Applicant argues that the reference demonstrates that DNA vaccines and killed virus vaccines could not be considered equivalent at the time of the invention. In response to this argument, it is noted that any person of skill in the art would have realized that DNA vaccines and killed virus vaccines are not equivalent. However, it is not clear how such a teaching would make the claimed invention unobvious. Applicant is again reminded that the DNA JEV vaccine was already taught by Paoletti et al. Because Goverdhan et al. teach that JEV and WNV are antigenically-related and are capable of eliciting cross-immune responses, one of skill in the art would have known to substitute the JEV prM/M, E with the WNV prM/M, E to achieve a predictable result, i.e., obtaining a vaccine capable of eliciting an immune response against WNV. Applicant argues that there is no teaching or suggestion as to whether there are any particular antigens or epitopes of the killed virus that can be applied to the recombinant vector vaccines. In response to this argument, it is noted that an obviousness-type rejection takes into account the knowledge as a whole available to one of skill in the art at the time the invention was made. The antigenicity of the WNV JEV prM/M, E and its use in DNA vaccines was taught by the prior art (see Chang et al., U.S. Patent No. 7,227,011, column 7, lines 22-67; of record). Applicant argues that Schultz et al. discusses the unpredictability of and difficulties associated with DNA vaccines. While Schultz et al. teach that several DNA vaccines were efficient in mice but less efficient in larger animals, such teachings are not applicable in the instant case because DNA vaccines against JEV and WNV were already used in the prior art and proven to be efficient in large animals.

For the reasons set forth above, Applicant’s arguments are not found persuasive and the rejection is maintained.

## *New Rejections*

### *Double Patenting*

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as

> to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.
>
> A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
>
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
>
> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-22, 29, and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 10-22, and 30 of copending Application No. 10/714,781. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets encompass an anti-WNV DNA vaccine encoding the WNV prM-M-E and its use to induce an immune response in animals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## ***Claim Rejections - 35 USC § 112, 2nd paragraph***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims recite both the genus of GenBank AF196835 and SEQ ID NO: 66, which is a species thereof (see the written description rejection above). Since it is not clear whether the claims are drawn to the GenBank AF196835 genus or the species of SEQ ID NO: 66, the metes and bounds of the claims cannot be determined and the claims are indefinite.

## *Conclusion*

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/
Examiner, Art Unit 1633